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Patent

Attorney Docket No. GEMS8081.040

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Brodnick, Donald et al.
Serial No.	:	09/661,064
Filing Date	:	September 13, 2000
Title	:	**PORTABLE ECG DEVICE WITH WIRELESS COMMUNICATION INTERFACE TO REMOTELY MONITOR PATIENTS AND METHOD OF USE**
Group Art No.	:	3762
Examiner	:	Khan, Omar A.

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 CFR §1.131

We, Donald E. Brodnick and Ian Rowlandson, being duly sworn, aver:

1. We are the inventors in the above-identified patent application.
2. We are both employees of GE Medical Systems in Waukesha, WI.
3. We have reviewed the above-described application.
4. That prior to December 21, 1999 we had conceived and had in our possession the invention described in the claims of this application.
5. The invention referenced in Paragraph 3 at least included a portable, on demand ECG monitor adapted to be connected to a plurality of lead wires, each lead wire having a transducer capable of receiving an ECG signal from a patient in a

standard 12-lead configuration; the ECG monitor having a processor to process ECG signals from the plurality of lead wires and produce standard 12-lead ECG data representative of cardiac condition of the patient; a wireless communications interface is included to be coupled to receive patient ECG data from the ECG monitor and capable of transmitting patient ECG data to a health care provider.

6. Attached hereto are (1) a two-page spreadsheet and (2) an eight-page High Level Marketing Specification, both created prior to December 21, 1999, and evidencing the conception of the invention prior to December 21, 1999.

7. From before December 21, 1999 to the filing of this application, we diligently worked toward a reduction to practice of the invention.

8. We have read the claims of the above referenced application, and we attest that what is described in the claims was conceived prior to December 21, 1999.

The present statements have been set forth to the best of our memories and recollection and we acknowledge and recognize that willful, false statements and the like are punishable by fine or imprisonment, or both.

Dated: 4-Apr-2003

Donald E. Brodnick

Donald E. Brodnick

Dated: 4 APR 2003

Ian Rowlandson

Project Element..... (from screening until discharge)	Purpose	Phases of introduction	Introduction date	Modality affected	Resources requrired	Unique Advantage?
Screening for plaque vulnerability. CRP combined with other modalities CVMR, Fast Ct	Detect before rupture. Reduce cost. Generate revenue. Disease management play	phase 4		CVMR, Fast CT		Yes.
ACI-TIPI combined with 12SL	Detect probability plaque rupture for triage of care.	now, phase 0	now	ECG	2-Jan	
Market 12SL w/ACI-TIPI to Zoll & Physio	Standard of care for early detection of ACS	phase 1		ECG	marketing / alliance management	
ACI-TIPI - improve accuracy. Cross-correlate with gold standard database. See pharma relationships.	ACI-TIPI without further development is not unique.	phase 4		ECG	Reddy group. 2 engineers	yes.
12SL in the home with transmission. SEERMC with cellular communication and 12 lead patch with education package. See Hopkins / NIH proposal.	early detection for post-MI patient. They delay care more than any patient group.	phase 4		ECG		
Serial comparison with baseline ECG.	Required for post-MI patient. Beneficial for all populations.	now, phase 0	now	MUSE	none	yes.
Baseline ECG / National database	Baseline ECG always improves accuracy in detecting ACS. Could leverage GE's large identity - Women's Health etc.	phase 2		MUSE	2 engineers plus lots of marketing working.	yes
Auto-routing via MUSE based on probability (see ACI-TIPI).	Reduce time to treatment. Alert proper audience.	phase 1		ECG / MUSE	not a lot	Yes (MUSE installed base)
Auto-scheduling Cath Lab. Models of utilization. Make it possible across facilities.	Reduce time to treatment.	phase 1		MUSE, CVIS, MacLab	2 engineers	Yes

ST Guard / ED decision support package, include continuous ST monitoring, enzyme data, H&P, ACC care guidelines	Reduce time to treatment. Lower cost.	phase 1		MUSE	2 engineers, luminary involvement	Yes
Stress-Echo; Need remote connectivity because ED does not know how to read and acquire data. Luminary sites are already doing.	Increase sensivity. Lower risk of law suit. Lower overall cost.	phase 2		Echo, Stress, CVIS		Yes
Stress-Nuclear (see above)	same as above	phase 2		Nuclear, Stress, CVIS		Yes
Hemodynamic monitoring from pre-hospital through to Cath Lab. Transport monitor with transmission and connectivity.	Reduce time to treatment. Patients going to primary PTCA are often unstable and need to be stabilized.	phase 4		monitoring		Yes.
12 lead continuous monitoring in the Cath Lab.	At this time, vessel patency can only be determined via 12 lead monitoring.	Phase 2		MacLab		maybe
12 lead on Imaging system; show match via ECG signature.	Drive focus of care on culprit lesion. Reduce time to treatment and Improve outcome.	phase 4		X-ray, MacLab		Yes
Discharge summary to office	Establish role in the office market. Sell boxes here too.	phase 2		ECG / MUSE		Yes

SEER 12
High Level Marketing Specification

Date:	Name:	Representing:
[redacted]	Carlos de la Huerga	VP, Diagnostics
[redacted]	Ian Rowlandson	Engineering
[redacted]	Frank Schmidt	Manufacturing
[redacted]	Kevin Lindsey	Finance
[redacted]	Dan Merritt	Marketing
[redacted]	Dave Perren	Service
[redacted]	Mike McLeod	Engineering Leader
[redacted]	Mark Langer	Marketing Leader
[redacted]		QA

[redacted]
Mark Langer

Final Draft - 5

SEER 12 High Level Specification

1.) Physical
-"Shirt Pocket" size and weight (less than 14oz).
-Beige, Light Gray, and MEI Red in color.
-Water resistant.
-Able to withstand 1 drop on to hard surface for all corners and faces.
-Belt clip option if no pouch is desired.
-Flash card and download connector (micro-D) under door for protection.
-Flash card not designed for patient removal.
-Separate battery compartment enclosed under door for protection.

2.) Operation Interface
-1 large patient event button provided in a location where it may be activated while worn under clothing.
-Skin preparation and cable check signals pass or fail on the LCD using a combination of skin impedance and cable impedance.
-AM.PM clock will be displayed for patient diary notation.
-Clock setting (remains in memory).
-The following options are programmable via flash card or download cable from review station:
  -Lead configuration set-up.
  -Filter settings.
  -Pacemaker detection on/off.
-Review station will advise user of memory card size required for programming selected.
-Display message if data in card has not been downloaded.

3.) Patient Cable
-Multi-use cable and leadwires for seven electrodes.
-Disposable V1 - V6 chest strip electrode for 12 lead recordings.
-Cable off and cable identification.
-Defibrillation protection.

4.) Front End Configurations
-True analog calibration pulse.
-The following options are programmable via flash card or download cable from review station:
  -Front-end will be programmable with .05 and .5 hertz high pass, 35, 55 hertz low pass filters.
  -.05 to 100 Hertz bandwidth may be selected for 12 leads (samples/sec).
  -2 or 3 bipolar leads (conventional Holter leads).
  -12 leads (conventional exercise leads).
-Pacemaker detection on 3 leads.

5.) Memory Options/ Capabilities
-4 Mb Flash Card:
  -2 ECG
-10 Mb Flash Card:
  -3 ECG, 12 medians/minute
  -3 ECG, 12 ECG/minute @ 55Hz
  -2 ECG, 12 ECG/minute @ 100 Hz
  -6 ECG
-20 Mb Flash Card:
  -12 ECG (external battery pack may be required)

6.) Data Interfaces
-Interface to Laser II via flash card and high speed cable. IR
-Interface to Laser I via SEER Flash AM.
-Interface to Centra via SEER Flash AM.
-Electrical Isolation will be provided by the SEER AM and review stations.
-Data Interface similar to SEER will be used so that SEER 12 will be compatible with older review stations.

7.) Analysis Capabilities
-Arrhythmia analysis.
-ST segment analysis.
-Pacemaker analysis.
-Automatic channel switching if high noise level or lead off detected.

12SL
HiRes

8.) Estimated Prices/Dates	Price	COG
-SEER 12	$2150	$700
-4 Mb Flash Card	$ 300	$189
-10 Mb Flash Card	$ 600	$400
-20 Mb Flash Card	$1200	$800
-Clinical Trials	[redacted]	
-1st Delivery		

9.) Future Developments
-An additional external battery pack will provide the ability to add rechargeable power for markets in India and China.
-48 and 72 hour operation using higher capacity cells. Lithium
-Signal to noise ratio recorded and trended each minute.
-Activity and body position monitor incorporated into left arm lead.
-Pulse oximetry transducer.
-QT and PR interval measurement.
-Mid-QRS analysis.
-Pediatric analysis program.
-XYZ leads.
-Continuous 12SL program.
-Alarm criteria for arrhythmia and ST segment levels.
-Home telemetry to telephone modem.

marquette

Project Number: 415857
Document Number: 415857-101

Diagnostic Division
Product Program Proposal

Project: SEER® MC
Originated By: Marge Keehn
Date: [redacted]

Revision History

Rev	Effective Date	Approvals			
		Marketing	Engineering	Unit Manager	QA
A	[redacted]				

Sections Changed in Current Revision

1. General description of the product

The SEER® MC is a second generation Marquette ambulatory solid state recorder. The intention of the product is to continue in the market with software and hardware innovations that solve customer problems in the acquisition of 24 hours of ambulatory clinical parameters.

2. Basic features and variations

- Ergonomic package that will fit in the majority of shirt pockets.
- Non-volatile, removable memory for application in an outreach setting.
- Various size memory cards for longer data acquisition and multiple-channel acquisition.
- 2-channel, 3-channel, or 12-lead acquisition.
- Programmable sampling rates for Holter, signal averaging, and 12-lead acquisition.
- The product should download to a variety of Marquette platforms.
- SEER® MC will be capable of transmitting a real time ECG test strip.

3. Expandability / future product considerations

- The product should be expandable by software in both algorithm development and features.
- Expandability via memory cards for life of the product.

4. The basic relationship of the new product to other existing or planned products

- The SEER® MC will need to interface to the MARS™ Unity Workstation, ABP device, the CENTRA®, and the LASER SXP® ambulatory ECG analysis and editing system. It should also interface to the MAC®8 resting ECG analysis system and CASE® 100 exercise testing system. In addition, the SEER® MC recorder should have the capability to download to all three platforms of the MARS™ workstation/Sun configuration, the Sparc 20, Sparc 5, and Sparc 4. Furthermore, the product should communicate with a standard PC for potential outreach communication link into a MARS™ workstation.
- SEER® MC should provide a means to interface / communicate with the ABP.
- A separate PPP is required to define the user interface on these host devices.

5. Target cost to manufacture and/or sales price and mark up

The target price of the product should be no greater than [redacted] the ideal cost [redacted] list price. Traditional market price of three times brings a cost of goods at approximately [redacted]

6. Risk analysis

[redacted]

7. Regulatory status

A 510(k) will need to be submitted to the FDA for the SEER® MC device.

8. Product justification

Marquette entered into the ambulatory solid state business in 1989. By doing so, several major problems were solved that were traditionally found in Holter monitoring. T[redacted]ed [redacted] The product also offered a very fast throughput, allowing an analysis to be done while the patient was wearing the device. This solved the single-tasking component of the editing station. When the SEER® recorder was combined with the LASER SXP® recorder, a high throughput offered a customer far more productivity in their cardiology department. The current SEER® recorder [redacted] and has been identified by the market to have several needed enhancements. These include: volatility of memory, size and shape of product, improved algorithm analysis performance, and portability of data. It is with these recommendations that the next generation solid state recorder is needed in a market place.

9. Competition

[redacted]

10. Target market

- Target markets include:
  - all customers who are purchasing [redacted]
  - all customers who currently own [redacted]
  - all customers who own a [redacted]n.
  - all customers who own a [redacted]
  - all customers who own a [redacted]em.
- In addition, customers who [redacted]hat want to do outreach, and have communication interface media utilizing [redacted]their outreach sites should be targeted.
- When leading with the recorder rather than the editing device, the target market it sophisticated, high and research-orientated facilities; typically beds greater than 300.
- An additional target market is smaller facilities that have the capability of linking to a large center that are responsible for outreach patients.

11. Return on investment

	[redacted]	[redacted]	[redacted]
Units			
Total World Wide Sales			
Gross Profit			

Based on following assumptions:

- Cost of goods [redacted]
- Selling price
- Product is launched by March [redacted]
- No FDA delays

12. Pull through potential

The SEER® MC recorder enhances the host devices by adding improved throughput and state of the art technology. Increased sales of host units would also be expected. In addition, cables and electrodes will be sold with this product.

13. Rational for regulatory classification

This will be identified in a 510(k) submittal.

The hospital based cardiograph line (VU, 8, PC, 6) will be replaced by four models that all emanate from the [redacted] platform. This platform provides a substantially lower cost of goods when compared to the current offering and is a key part of the strategy to increase revenues in the Cardiographs and Stress lines over the next few years. [redacted] is slated for release in Q2. This product will be offered in both monochrome and color versions. It contains a new integrated thermal writer and acquisition module, AM-11[redacted] will replace the Mac VU and Mac 8 (although marketing may decide to continue shipping this product for awhile). After release of the 5000, a subset of this team will turn its attention to the development o[redacted] and [redacted] These are needed before the end of the fiscal year. The rest of the team will initiate aggressive development of the [redacted] wireless option. At the lower end a cost reduced version of CardioSmart will be released in October to fill in the gap between [redacted] and [redacted]. A stress option (CardioSmart C ST) for this product will also be developed.

In the stress line, the new Case 8000 is to release in Q2 and will replace Case 16. This product, a joint development between Milwaukee and Freiburg, is based on Windows NT and CardioSys but also contains the thermal writer and acquisition module from the Mac 5000. It will contain new decision support tools and be capable of interacting with MUSE to retrieve and display previous exercise tests. The Milwaukee Case team will begin development of Max-II (Max-I replacement) after the 8000 release. During the Max-II product definition stage engineers from this team may be called upon to assist with NT device drivers for the Mars NT port.

ECG acquisition for all new hospital resting and stress products will be accomplished by one new device, AM-114. This device will be supplied with 16-lead acquisition capability as a standard feature. It will be smaller and cheaper than the current AM-5. Lead wires for the AM-114 will be based on Multi-link® and require no new tooling.

The 12-lead option for the recently released SEER MC will be released in Q2. This will allow continuous/sequential 12 leads to be acquired and read into MUSE or QT Guard. Software for remote transmission of 12 leads to MUSE from a Windows CE device will also be available. In Q1 SEER MC will be interfaced to a Holter system from Bio-medical Systems to create a product that can be offered with the CardioSys 5.0 release as a low-end Holter solution. This will likely be replaced with a MARS product once the NT port is ready. In the middle of the year, some members of the SEER MC team will embark on an event recorder project.

The Mars system has been greatly stabilized and version 4.0 provides the necessary base feature set. In the first quarter the team will get the software under version control and begin to port MARS to Windows NT. The result will allow other teams (CIC, Cath Lab) to utilize the MARS code in their products as well as allow us to offer a PC based solution for Holter. The MARS software will also be offered on new Sun platforms, which will extend the product range. Later in the year, development of new features for QT, Waterfall display, and afib detection will commence.

The new hospital defibrillator, Marquette Responder 3000, will release in Q1. The first release will include Color Display, Printer, AED/manual mode, $etCO_2$, and 12SL. The 2nd release is planned to deliver Pacer, SpO_2, voice prompts, and data transfer to MUSE. The Responder 1000 team will initiate development of the Dash add on defibrillator. The EMS team will develop an EMS workstation with connection to MUSE.

For MUSE, final releases of 5.A (Q2)will enable MARS/MUSE interface and Email capability. Version 5.B (Q4) will deliver key market parity functions including ACC Registry, receive and store DICOM images, editable coronary tree, heart diagram, LV Analysis and Vessel Stenosis. New physician interface software (from Cyberpulse) is being integrated exclusively to the MUSE® system for Echo and Cath applications (unveil at AHA). A new function providing for exporting data from MUSE to a SQL database (Q4) is being prototyped. Enhanced *Remote Support* (Q4) will provide better service at lower costs. *Remote Editing* (Q4) will enable Marquette to provide an outsourcing service (aka *Lobby MUSE*) for customers who don't want to completely own and staff a full system on site. A configuration tool for HIS interfaces (Q2) will enable customer IS staff to adapt Marquette's interface to site specifications; reduce the